K082851
Page 1 of 2

NOV 19 2008

GE Healthcare
510(K) Premarket Notification Submission

510(k) Summary

In accordance with 21 CFR 807.92 the following summary of information is provided:

Date:	September 26, 2008
Submitter:	GE Medical Systems Information Technologies 9900 Innovation Drive Wauwatosa, WI 53226
Primary Contact Person:	Matthias Buerger Director QA/RA - Diagnostic Cardiology GE Medical Systems Information Technologies RP-2122 9900 Innovation Drive Wauwatosa, WI 53226 Telephone: 414-721-1438 Fax: 414-721-3863 E-mail: Matthias.buerger@ge.com
Secondary Contacts:	Margaret Mucha Regulatory Affairs Leader GE Medical Systems Information Technologies RP-2122 9900 Innovation Drive Wauwatosa, WI 53226 Telephone: 262-548-2514 Fax: 414-721-3863 E-mail: margaret.mucha@ge.com
	Renee Thornborough QA Leader GE Medical Systems Information Technologies RP-2122 9900 Innovation Drive Wauwatosa, WI 53226 Telephone: 414-721-3954 Fax: 414-721-3899 E-mail: renee.thornborough@ge.com
Device: Trade Name:	Multilink Cable and Leadwire Systems
Common/Usual Name:	Multilink Cable and Leadwire Systems
Classification Names:	Patient transducer and electrode cable
Product Code:	890.2900 / Patient transducer and electrode cable / DSA
Predicate Device(s):	Multilink Cable and Leadwire Systems (K980582)
Device Description:	**The purpose and function of the device has not changed** The Multilink Cables and Leadwires are part of the GE Medical Systems Information Technologies line of supplies and accessories used to transmit patient ECG and RESP signals to diagnostic and monitoring equipment. The system is designed to provide a family of leadwires that will link the patient and patient cable system. Leadwires are available in multiple lengths and in multiple lead sets. Patient end terminations are available in Snap, Banana, Mactrode, or Grabber configurations. The multi-lead individual set design allows single leadwires to

	be individually removed and replaced as necessary. Mulilink leadwires are also available in a radiotranslucent version.
Intended Use:	**The Intended Use has been modified to include description of users and location of use** Multi-Link Cable and Lead Wire Systems are electrocardiograph cable systems used to transmit signals from patient surface electrodes to various electrocardiograph recorders/monitors for both diagnostic and monitoring purposes. Use is limited by the indications for use of the connected monitoring or diagnostic equipment. Multilink Cables and Lead Wire Systems are intended to be used by trained operators in a medical professional's environment

Technology:	The Multilink Cable and Leadwire Systems employs the same functional scientific technology as its predicate device.
Determination of Substantial Equivalence:	Summary of Non-Clinical Tests: *The* Multilink Cable and Leadwire Systems *and its applications comply with voluntary standards as detailed in Section 9, 11 and 17 of this premarket submission. The following quality assurance measures were applied to the development of the system:* • *Risk Analysis* • *Requirements Reviews* • *Design Reviews* • *Testing on unit level (Module verification)* • *Integration testing (System verification)* • *Final acceptance testing (Validation)* • *Performance testing (Verification)* • *Safety testing (Verification)* Summary of Clinical Tests: The subject of this premarket submission, Multilink Cable and Leadwire Systems, did not require clinical studies to support substantial equivalence.
Conclusion:	GE Healthcare considers the Multilink Cable and Leadwire Systems to be as safe, as effective, and performance is substantially equivalent to the predicate device(s).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 19 2008

GE Medical Systems Information Technologies
c/o Matthias Buerger
Director QA/RA – Diagnostic Cardiology
9900 Innovation Drive
Wauwatosa, WI 53226

Re: K082851
Multilink Cable and Leadwire Systems
Regulation Number: 21 CFR 870.2900
Regulation Name: Transducer and Electrode Patient Cable (including connector)
Regulatory Class: II
Product Code: DSA
Dated: September 26, 2008
Received: September 26, 2008

Dear Mr. Buerger:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

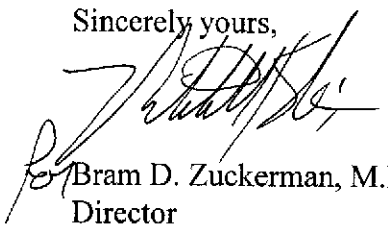
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K082851
Page 1 of 1

GE Healthcare
510(K) Premarket Notification Submission

510(k) Number (if known): _____

Device Name: **Multilink Cable and Leadwire Systems**

Indications for Use:

Multi-Link Cable and Lead Wire Systems are electrocardiograph cable systems used to transmit signals from patient surface electrodes to various electrocardiograph recorders/monitors for both diagnostic and monitoring purposes. Use is limited by the indications for use of the connected monitoring or diagnostic equipment.

Multilink Cables and Lead Wire Systems are intended to be used by trained operators in a medical professional's environment.

Prescription Use_X____ AND/OR Over-The-Counter Use_____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for BZuckerman

(Division Sign-Off) 11/19/08
Division of Cardiovascular Devices

510(k) Number K082851